IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civil Action No. 4:21-cv-01058-P

DEFENDANT FOOD AND DRUG ADMINISTRATION'S RESPONSE TO PFIZER INC'S MOTION FOR LEAVE TO INTERVENE FOR A LIMITED PURPOSE

Pursuant to the Court's Order of January 21, 2022, Dkt. No. 43, Defendant Food and Drug Administration ("FDA") reports that it consents to Pfizer Inc.'s Motion for Leave to Intervene for a Limited Purpose ("Pfizer's Motion to Intervene" or "Motion"), Dkt. Nos. 40-41, insofar as Pfizer moves for permissive intervention under Federal Rule of Civil Procedure 24(b).

As Pfizer noted in its Motion, "it is the Government's province to make the relevant determinations under FOIA." Dkt. No. 40 at 2. However, due to the unprecedented speed with which the Court has ordered FDA to process the records at issue, FDA anticipates that coordination with Pfizer to obtain the company's views as to which portions of the records are subject to Exemption 4, the Trade Secrets Act ("TSA"), 18 U.S.C. § 1905, or other statutory protections will be a necessary component of the agency's endeavors to meet the extraordinary exigencies of this case. *See* Defendant's Motion to Partially Modify Scheduling Order, Dkt. No.

37, at 6 (explaining that these efforts are already underway, and anticipated to evolve). Pfizer's participation in this matter will facilitate these necessary communications.

Additionally, as FDA previously explained, if the agency determines not to withhold information that might be confidential commercial information, it is required under some circumstances to provide notice to the company that submitted the information. *See, e.g.,* 21 C.F.R. §§ 20.47, 20.48, 20.61(e). The submitter in that circumstance may challenge the disclosure under the Administrative Procedure Act (a "reverse FOIA" claim), and may assert a violation of another statute such as the TSA . *See Doe, 1 v. Federal Election Comm'n*, 920 F.3d 866, 872 (D.C. Cir. 2019) (holding that, because "FOIA is a disclosure statute," "the agency cannot possibly violate FOIA" in disclosing information (citing *Chrysler v. Brown*, 441 U.S. 281, 292 (1979)); *see also Northrop Grumman Sys. Corp. v. NASA*, 346 F. Supp. 3d 109, 116 (D.D.C. 2018) (holding that in "reverse-FOIA cases" "an aggrieved party may bring an action under the APA to enjoin an agency from releasing proprietary information under FOIA in violation of the Trade Secrets Act" or on the basis that disclosure is otherwise "unlawful or arbitrary and capricious 'agency action.'"). Thus, this case may require expedited judicial resolution of any "reverse FOIA" issues that may arise. It would further judicial efficiency to resolve in the same case the FOIA claim and any related "reverse FOIA" claims cognizable under the APA, and Pfizer's participation in these proceedings will further this interest.

Accordingly, FDA shares Pfizer's view that, in the unusual and indeed extraordinary circumstances here presented, Pfizer's intervention would facilitate an orderly resolution of this matter, and consents to Pfizer's intervention pursuant to Rule 24(b).

Dated: January 25, 2022 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 25, 2022, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

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